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Appendix A: Chemical Safety for Sustainability

Part 1: Chemical Safety for Sustainability Strategic Research Action Plan, 2019 - 2022

Part 2: CSS Scientific Portfolio Overview

Part 3: CSS Publications

Part 4: CSS Models, databases and tools

Appendix B: Human and Environmental Risk Assessment

Part 1: Human and Environmental Risk Assessment Strategic Research Action Plan, 2019-2022

Part 2: HERA Scientific Portfolio Overview

Part 3: HERA Portfolio of Delivered Products

Appendix C: New Approach Methods Work Plan: Reducing use of animals in chemical testing, U.S. EPA June 2020

Appendix D: Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Within the TSCA Program, U.S. EPA June 2018

Connection information (Zoom): https://us02web.zoom.us/j/89685201943

Meeting ID (if prompted): 896 8520 1943 Password: 757326

Meeting Agenda

Tuesday February 2, 2021 (connection information in Table of Contents)

TIME (EST)	AGENDA ACTIVITY	PRESENTER			
12:00 - 12:10	Meeting kick off/FACA rules/expectations/logistics	Tom Tracy, DFO, OSAPE			
12:10- 12:15	ORD Welcome	Jennifer Orme-Zavaleta, ORD Principal DAA for Science			
12:15 - 12:25	Subcommittee Chair Opening Remarks and Introductions	Katrina Waters, Chair			
12:25 - 12:45	CSS NAMs Research and Development Portfolio: Connecting the Dots to Relevance and Acceptance	Jeff Frithsen, NPD, CSS			
12:45 - 1:05	HERA Advancing the Science and Practice of Risk Assessment	Samantha Jones, NPD, HERA			
1:05 - 1:20	Moving from the StRAPs to Implementation by ORD Investigators	Jill Franzosa, ACD, CCTE			
1:20 - 1:50	Evolution of NAMs in EPA: From Research to Application	Rusty Thomas, CD, CCTE			
1:50 - 2:15	BOSC Subcommittee discussion and Qs/As	Katrina Waters, Chair			
2:15 - 2:30	NAMs Research Introduction with Charge Question	Jeff Frithsen, NPD, CSS			
2:30 – 2:45	BREAK & Transition to Virtual Break-out Rooms				
Note: Eac	CSS SESSION 1: CONCURRENT PRESENTATIONS ON NAM research topic will be presented in 25 minutes including t				
Note, Laci	SESSION A: Emerging Approaches to Ha				
	1. High Throughput Phenotypic Profiling	Joshua Harrill, CCTE			
	2. High Throughput Transcriptomics	Logan Everett, CCTE			
	3. Retrofitting <i>in vitro</i> Systems with Metabolic	Logan Everett, cere			
	Competence	Chad Deisenroth, CCTE			
	SESSION B: NAMs for Exposure				
	1. High Throughput Exposure Models (SEEM)	John Wambaugh, CCTE			
	2. High Throughput Toxicokinetic Models and IVIVE	Barbara Wetmore, CCTE			
	3. Non-Targeted Analysis	Jon Sobus, CCTE			
	SESSION C: NAMs for Ecotoxicological	<u> </u>			
2:45 - 4:00	1. Approaches and Models for Species Extrapolation	Carlie LaLone, CCTE			
2.10 1.00	2. Novel <i>in vitro</i> Methods for Ecological Species	Brett Blackwell, CCTE			
	3. High Throughput Transcriptomics: A Multi-Species	· · · · · · · · · · · · · · · · · · ·			
	Approach	Kevin Flynn, CCTE			
	SESSION D: System-specific Models and Approaches				
	SESSION D: System-specific Models and	Approaches			
	SESSION D: System-specific Models and 1. Development and Harmonization of Organotypic/Co-	Approaches			
	1. Development and Harmonization of Organotypic/Co- Culture Models and Assays to Improve Throughput and <i>In Vivo</i> Relevance in Inhaled Chemical Testing				
	 Development and Harmonization of Organotypic/Co- Culture Models and Assays to Improve Throughput and In Vivo Relevance in Inhaled Chemical Testing An Approach Using NAMs for the Evaluation of 	Shaun McCullough, CPHEA			
	Development and Harmonization of Organotypic/Co- Culture Models and Assays to Improve Throughput and In Vivo Relevance in Inhaled Chemical Testing An Approach Using NAMs for the Evaluation of Inhalation Toxicity in OCSPP Chemical Registrations				
	 Development and Harmonization of Organotypic/Co- Culture Models and Assays to Improve Throughput and In Vivo Relevance in Inhaled Chemical Testing An Approach Using NAMs for the Evaluation of 	Shaun McCullough, CPHEA			
4:00 - 5:00	 Development and Harmonization of Organotypic/Co- Culture Models and Assays to Improve Throughput and In Vivo Relevance in Inhaled Chemical Testing An Approach Using NAMs for the Evaluation of Inhalation Toxicity in OCSPP Chemical Registrations Neurovascular Unit Modeling and Blood Brain Barrier 	Shaun McCullough, CPHEA Mark Higuchi, CPHEA			

Wednesday February 3, 2021 (connection information in Table of Contents)

TIME (EST)	AGENDA ACTIVITY	PRESENTER
12:00 - 12:10	Public comments	Tom Tracy, DFO, OSAPE
12:10- 12:15	BOSC Subcommittee Chair Opening Remarks	Katrina Waters, Chair
cs	S SESSION 2: APPLICATIONS OF NAMS TO AGENCY AND S	STATE PROGRAMS
12:15 - 12:30	NAMs Applications Introduction with Charge Question	Jeff Frithsen, NPD, CSS
12:30 - 1:00	OCSPP-TSCA Inventory: Prioritization Proof of Concept	Richard Judson, CCTE
1:00 - 1:30	Developmental Neurotoxicity (DNT) <i>in vitro</i> Battery as an Alternative to DNT <i>in vivo</i> Guideline Studies Used by OPP	Tim Shafer, CCTE
1:30 - 2:00	Implementing a Workflow for Exposure Screening of Drinking Water Contaminants of Concern	Kristin Isaacs, CCTE
2:00 - 2:30	Application of NAMs and AOPs to Surface Water Surveillance and Monitoring in the Great Lakes (EPA Region 5) and a Western River (EPA Region 8)	Dan Villeneuve, CCTE
2:30 – 2:45	BREAK	
2:45 – 3:15	BOSC Subcommittee discussion and Qs/As	Katrina Waters, Chair
	CSS SESSION 3: DEMONSTRATIONS OF TOO	LS
3:15 - 3:30	NAMs Tools Demo Intro with Charge Question	Jeff Frithsen, NPD, CSS
3:30 - 4:00	CompTox Chemicals Dashboard	Tony Williams, CCTE
4:00 - 4:30	SeqAPASS	Carlie LaLone, CCTE
4:30 - 5:00	Factotum: Curation of Exposure-Relevant Public Data	Kristin Isaacs, CCTE
5:00 - 5:30	BOSC Subcommittee discussion and Qs/As	Katrina Waters, Chair
5:30	ADJOURN	

Thursday February 4, 2021 (connection information in Table of Contents)

TIME (EST)	AGENDA ACTIVITY	PRESENTER	
12:00 – 12:05	Meeting kick off/FACA rules/expectations/logistics	Tom Tracy, DFO, OSAPE	
12:05- 12:15	BOSC Subcommittee Chair Opening Remarks	Katrina Waters, Chair	
12:15 – 12:25	Connecting Assessment Needs to HERA Research	Beth Owens, PANPD, HERA	
12:25 – 12:35	ORD Implementation	Wayne Cascio, CD, CPHEA	
12:35 – 12:50	BOSC Subcommittee discussion and Qs/As	Katrina Waters, Chair	
	HERA SESSION 1: Applying NAMS to Inform HERA	Assessments	
	Applying NAMs to Inform HERA Assessments with		
12:50 - 1:00	Charge Question	Luci Lizarraga, CPHEA	
1:00 - 1:20	Advancing Read-across in HERA	Luci Lizarraga, CPHEA	
1:20 - 1:40	Filling Metabolism Data Gaps in Read-across	Grace Patlewicz, CCTE	
1:40 - 2:00	Adverse Outcome Pathway (AOP) Footprinting for Mixtures	Jason Lambert, CCTE	
2:00 – 2:40	BOSC Subcommittee discussion and Qs/As	Katrina Waters, Chair	
2:40 - 2:50	BREAK		
	HERA SESSION 2: Advancing Systematic Review	Methods	
2:50 – 3:05	Advancing SR Methods and Tools Intro with Charge Question	Kris Thayer, CPHEA	
3:05 – 3:25	Organizing and Evaluating Mechanistic Evidence	Catherine Gibbons, CPHEA	
3:25 – 3:45	Automated Data Extraction	Michele Taylor, CPHEA	
3:45 – 4:05	Semantic Ontology Mapping	Michelle Angrish, CPHEA	
4:05 – 4:25	Application of Systematic Evidence Map Methods to Characterize Available Evidence for PFAS	Laura Carlson, CPHEA	
4:25 – 5:00	BOSC Subcommittee discussion and Qs/As	Katrina Waters, Chair	
5:00	ADJOURN		

Friday February 5, 2021 (connection information in Table of Contents)

TIME (EST)	AGENDA ACTIVITY	PRESENTER	
12:00 – 12:05	Meeting kick off/FACA rules/expectations/logistics	Tom Tracy, DFO, OSAPE	
12:05 – 12:20	BOSC Subcommittee Chair Opening Remarks	Katrina Waters, Chair	
	HERA SESSION 3: Advancing Dose-Response Analyse	es and Tools	
12:20 – 12:35	Advancing Dose-Response Intro with Charge Question	John Vandenberg, CPHEA	
12:35 – 12:55	Multi-path Particle Dosimetry (MPPD) Model	Annie Jarabek, CPHEA	
12:55 – 1:15	Bayesian Model Averaging and BMDS 3.2	Allen Davis, CPHEA	
1:15 – 1:35	Approximate Probabilistic Analysis (APROBA)	Todd Blessinger, CPHEA	
1:35 – 2:10	BOSC Subcommittee discussion and Qs/As	Katrina Waters, Chair	
	CSS-HERA Closing		
2:10 – 2:30	Closing Statements and Responses	Samantha Jones, NPD, HERA	
2.10 2.30	crossing statements and nesponses	Jeff Frithsen, NPD, CSS	
2:30 - 5:00	BOSC Subcommittee Deliberations	Katrina Waters, Chair	
5:00	ADJOURN		

BOSC Subcommittee Roster

Designated Federal Official

Tom TracyOffice of Science Advisor, Policy, and Engagement Office of Research and Development U.S. EPA

Members

Name	Affiliation	Expertise	Background
(Chair) Katrina Waters, Ph.D.	Division Director, Biological Sciences Research, Pacific Northwest National Laboratory {WA Region 10}	Systems biology Pharmacokinetics Molecular biology/genomics Endocrinology Bioinformatics	Dr. Waters' expertise and research interests are focused around the analysis and biological interpretation of global gene and protein expression data related to mechanism of action or applied research. In addition, she has several years of experience developing and carrying out molecular and biochemical assays in the laboratory to test hypotheses resulting from microarray experiments.
(Vice Chair) James Stevens, Ph.D.	President, Paradox Found LLC (NC Region 4)	Computational toxicology/biology High-throughput bioassays Molecular toxicology Pharmacology Systems biology	Dr. Stevens' research interests are in the areas of predictive and molecular and investigative toxicology and adverse drug reactions. He has studied the role of gene expression in mechanisms of cell injury for over two decades and was among the first to adopt gene expression analysis to understand mechanisms of toxicity. He was a member of the Board of Directors for Upstate Biotechnology and the Interim Vice President for Research and Development for Argonex Pharmaceuticals.
Anthony Bahinski, Ph.D., MBA, FAHA	Global Head, Safety Pharmacology, GlaxoSmithKline (PA Region 3)	Biology Computational toxicology/biology Emerging materials (nanotechnology) Pharmacokinetics Toxicology	Dr. Bahinski has expertise in safety pharmacology, drug discovery and development, cardiac physiology and pharmacology, and electrophysiology. His research includes the development of organ-on-a-chip technology for efficacy, safety, and toxicity evaluation of drugs, biologics, environmental toxins, and nanoparticles, including mechanistic studies and disease models. Dr. Bahinski is currently a member of the Science Board of the U.S. Food and Drug Administration.

Name	Affiliation	Expertise	Background
Richard Becker, Ph.D. DABT	Senior Toxicologist, American Chemistry Council (DC Region 3)	Exposure science Risk assessment Toxicology	Dr. Becker's expertise is in toxicology, risk assessment, alternatives to animal testing, prediction models, and method validation. He directs the American Chemistry Council's Long-Range Research Initiative, a research program designed to modernize and improve chemical safety assessments. Dr. Becker is a Diplomate of the American Board of Toxicology and a member of the Society of Toxicology, the American Chemical Society, and the Society for Risk Analysis.
Juan Colberg, Ph.D.	Senior Director of Chemical Technology & Innovation and Green Chemistry Program Leader, Pfizer Inc. Worldwide Research and Development (CT Region 1)	Chemical risk assessment Green chemistry Life cycle analysis Risk assessment Sustainability	Dr. Colberg's research interests are research program evaluation, chemical safety for sustainability, human health risk assessment, green chemistry, and chemical risk assessment and management. At Pfizer, he leads the chemistry technologies efforts to evaluate and develop alliances with external partners to deliver platform technologies suitable for greener and more environmentally sound chemical manufacturing of products.
<u>Richard Di Giulio, Ph.D.,</u> <u>MS</u>	Sally Kleberg Professor of Environmental Toxicology, Duke University (NC Region 4)	Biology Ecology Risk assessment Toxicology	Dr. Di Giulio provides expertise in environmental toxicology, ecotoxicology, and risk assessment. His research interests are the effects, including mechanisms, of environmental pollutants on aquatic organisms and humans, and on interconnections between ecological and human health. Dr. Di Giulio has fifteen years' experience directing both the Superfund Research Center and the University Program in Environmental Health at Duke University (supported by the National Institute of Environmental Health Sciences). In addition, he has eight years' experience as Co-Principal Investigator of Duke's Center for the Environmental Implications of Nanotechnology (supported by the National Science Foundation and U.S. Environmental Protection Agency).

Name	Affiliation	Expertise	Background
Chris Gennings, Ph.D.	Research Professor, Icahn School of Medicine at Mount Sinai (NY Region 2)	Information science Human health risk assessment (chemical mixtures risk assessment)	Dr. Genning's research interests focus on chemical mixtures risk assessment including developing and implementing statistical techniques useful for estimating risk assessment of exposure to combinations of chemicals; designing economical study designs for mixtures of many chemicals; statistical modeling of pesticide mixtures; and integration of mixtures toxicology and statistics. She is the founding director of a T32 training grant from the National Institute of Environmental Health Sciences (NIEHS) in Environmental Statistics, focused on the integration of mixtures toxicology and statistical methods. Her research has been supported by NIEHS, U.S. Environmental Protection Agency, World Health Organization, National Institute of Child Health and Human Development, and the Health Effects Institute.
Dale Johnson, Pharm.D., Ph.D., DABT	President and CEO, Emiliem, Inc.; Adjunct Professor, University of Michigan; Adjunct Professor, University of California, Berkeley (MI Region 5, CA Region 9)	Computational toxicology/biology Pharmacokinetics Risk assessment	Dr. Johnson has technical expertise in computational toxicology and quantitative structure-activity relationship (QSAR) modeling. At the University of California, Berkeley, Dr. Johnson's research focuses on predictive toxicology and network pharmacology utilizing computational methodology to analyze chemical-biological interactions, model structure activity relationships, and analyze perturbations in systems biology pathways.
<u>Daland Juberg, Ph.D.,</u> <u>ATS</u>	Human Health Science Policy Leader, Corteva (IN Region 5)	Toxicology Exposure science Public health (children's health) Risk assessment	Dr. Juberg has expertise in public health, toxicology, children's health, exposure science, risk assessment, sustainability, science policy, and risk communication. He has diverse industrial sector and consulting experiences spanning a number of scientific disciplines that are central to the evaluation and protection of human health and the environment. Dr. Juberg is an active member of the Society of Toxicology and a Fellow of the Academy of Toxicological Sciences.

Name	Affiliation	Expertise	Background
Juleen Lam, Ph.D., MHS, MS	Assistant Professor, California State University, East Bay (CA Region 9)	Epidemiology Human health risk assessment Public health Risk assessment Toxicology	Dr. Lam has expertise in environmental health, environmental health policy, biostatistics, systematic review, and risk assessment. One key area of her research involves the development, improvement, and implementation of evidence-based systematic review methodology tailored specifically for use in environmental health to inform science-based policy- and decision-making. Her other research interests include advancing quantitative tools in risk assessment as well as the incorporation of high throughput screening approaches to predicting human toxicity. Dr. Lam has previously worked with the U.S. Environmental Protection Agency in the Office of Policy.
Timothy Malloy, J.D.	Professor, University of California, Los Angeles (CA Region 9)	Decision science/analysis/value of information Public health Risk assessment Social science Toxicology Behavioral science (risk communication)	Mr. Malloy's research interests include the application of science and engineering in regulatory and business settings, including nanotechnology, emerging materials, public health, risk assessment, sustainability, toxicology, law and social science, and decision science. One aspect of his research deals with the value and limits of applying decision analysis to public and private decisions regarding identification and evaluation of safer chemicals.
Jennifer McPartland, Ph.D.	Senior Scientist, Environmental Defense Fund (DC Region 3)	Biology Chemical risk assessment Computational toxicology/biology High-throughput bioassays Toxicology	Dr. McPartland works to identify and reduce chemical exposures harmful to human health and the environment. Her work at Environmental Defense Fund includes science, policy, and marketplace-related initiatives. In each of these areas, Dr. McPartland works with diverse groups of stakeholders to determine how improvements can be made to understand and ultimately reduce or eliminate toxic chemical exposures. Dr. McPartland has focused on new computational toxicology methods being developed by the U.S. Environmental Protection Agency to better understand and predict chemical hazard and risk, as well as efforts by the agency to apply systematic review methods in chemical assessment.
Jane Rose, Ph.D.	Principal Scientist, Procter and Gamble Company (OH Region 5)	Human health risk assessment Risk assessment Toxicology	Dr. Rose has expertise in chemical risk assessment, inhalation toxicology exposure assessments, and the development of threshold of toxicological concern approaches. She has established inhalation exposure modeling approaches for consumer products and integrated these approaches into the industry aggregate exposure framework. Dr. Rose is also the leader of the Inhalation Safety Expert Team at The Proctor and Gamble Company.

Name	Affiliation	Expertise	Background
Gina Solomaon, M.D., MPH	Principal Investigator, Public Health Institute; Clinical Professor, University of California, San Francisco (CA Region 9)	Endocrinology Environmental health sciences Public health (children's health) Risk assessment	Dr. Solomon has experience working for a non-governmental organization, hospitals, a research institute, and universities. She addresses technical issues as well as policy. Dr. Solomon's prior work has included research on diesel exhaust and asthma, endocrine disrupting chemicals, pesticides, environmental contaminants in New Orleans after Hurricane Katrina, the health implications of the 2010 Gulf oil spill, and the health effects of climate change.
Ponisseril Somasundaran, Ph.D., MS	President, Somasundaran, Inc.; La von Duddleson Krumb Professor, Columbia University (NY Region 2)	Emerging materials Toxicology	Dr. Somasundaran has expertise in green chemistry, energy, waste water treatment, and nanotoxicity/environmental effects of nanoparticles. He specializes in surface and colloid chemistry. His research has been concerned with a wide spectrum of environmental problems including greener chemistry, enhanced oil recovery, remediation, tar sands, coal cleaning, sludge treatment, waste water treatment, and nanotoxicity.
Donna Vorhees, Sc.D.	Director of Energy Research, Health Effects Institute; Adjunct Assistant Professor, Boston University (MA Region 1)	Exposure science Human health risk assessment	Dr. Vorhees specializes in multi-pathway exposure assessment and human health risk assessment of chemicals in indoor and outdoor environments. She has 20 years of consulting experience and has conducted deterministic and probabilistic exposure and risk modeling for chemicals, such as polychlorinated biphenyls, dioxins and furans, petroleum hydrocarbons, volatile organic compounds, and metals (e.g., arsenic, lead, and mercury).
Clifford P. Weisel, Ph.D.	Professor, Exposure Science, Environmental and Occupational Health Sciences Institute, Rutgers University (NJ Region 2)	Exposure science Human health risk assessment	Dr. Weisel's research experience includes the determination of biomarkers of exposure, measurement of multiroute exposures to volatile organic compounds and disinfection byproducts in drinking water, exposure to children, the role of air pollution in exacerbation of asthma, exposures within modes of transportation, the sources of pollutants to indoor air and their contribution to personal exposure, and the how exposures affect the lung microbiome.

Name	Affiliation	Expertise	Background
Mark Wiesner, Ph.D.	James B. Duke Professor of Civil and Environmental Engineering, Duke University; Chair, Department of Civil and Environmental Engineering, Duke University; Director, Center for the Environmental Implications of NanoTechnology (CEINT) (NC Region 4)	Emerging materials	Dr. Wiesner's research interests include membrane processes, nanostructured materials, transport and fate of nanomaterials in the environment, colloidal and interfacial processes, and environmental systems analysis. Dr. Wiesner's research pioneered the application of membrane processes to environmental separations and water treatment. He co-edited and -authored the book Water Treatment Membrane Process, and served as the founding Chair of the American Water Works Association's Membrane Research Committee. He also co-edited and -authored the book Environmental Nanotechnologies.

Office of Research and Development

Within the EPA's Office of Research and Development, the national research programs partner with the ORD centers to carry out the research outlined in the StRAP.

Center for Public Health & Environmental Assessment (CPHEA)

Provides the science needed to understand the complex interrelationship between people and nature in support of assessments and policy to protect human health and ecological integrity.

Center for Computational Toxicology & Exposure (CCTE)

CCTE researchers are developing and applying sulting edge innovations in methods to rapidly evaluate chemical toxicity, transport, and exposure to people and environments.

Chemical Safety for Sustainability

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Health and Environmental Risk Assessment

Center for Environmental Measurement & Modeling (CEMM)

Provides scientific expertise and leadership in the development and application of complex computational models that provide precise and detailed predictions of the activity of contaminants in the environment.

Center for Environmental Solutions & Emergency Response (CESER)

Plans, coordinates and conducts an applied, customer-driven, national research and development program to improve decision making by EPA, federal, state, tribal and local agencies, when faced with challenging environmental problems in the built environment.

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CSS National Research Program Review Charge Questions

Introduction: The February 2021 meeting of the CSS-HERA Subcommittee of the Board of Scientific Counselors (BOSC) will review that portion of the CSS portfolio involved in the development and application of New Approach Methodologies (NAMs). The focus of the review is on the implementation of research and development that was outlined at the strategic level in the CSS Strategic Research Action Plan for FY19-22, as previously reviewed by the BOSC.

Charge Question 1

The CSS portfolio advances New Approach Methods (NAMs) across multiple research areas related to chemical evaluation and risk assessment. CSS Session 1 presents selected research activities to highlight NAMs development for hazard evaluation, exposure, ecotoxicology, and human-system models. Please provide specific suggestions or recommendations to improve approaches to advance the development and testing of NAMs conducted under the CSS program.

Charge Question 2

A key long-term objective of the CSS program is to increase the pace of chemical assessment through the incorporation of NAMs into decision making by EPA programs and regions and other stakeholders. CSS Session 2 presents examples of NAMs implementation that address specific, articulated needs of Agency partners. Please comment on the extent to which these selected research activities have the appropriate approach, structure, and components to increase confidence in, and to facilitate use of, NAMs in Agency decision making.

Charge Question 3

CSS continues to develop and evolve multiple publicly-available data resources, analytical tools, and predictive models to facilitate the dissemination and use of chemical-safety information tailored to meeting specific user's needs. The long-term intent is for these CSS-supported platforms to provide a comprehensive resource to support the needs of our partners. CSS Session 3 presents examples of CSS information resources, models, and tools. Please provide suggestions or recommendations regarding how these CSS products can be improved and best implemented to serve EPA partners and external stakeholders?

HERA National Research Program Review Charge Questions

Charge Question 1:

As NAMs' science advances, risk assessors still encounter many chemicals with little-to-no data that require assessment. Research is required to translate and build confidence in the application of these NAMs in HERA science assessment contexts. Building on the case study examples, please provide suggestions or recommendations on how the planned research can best advance the integration of NAM data streams and approaches in HERA science assessments. [Research Area 3, Output 3.1]

Charge Question 2:

Incorporating the principles of systematic review into the HERA portfolio of assessment products has been a goal of the HERA program for the last several years. In order to achieve this goal, the HERA program intends to advance the field of systematic review more broadly. Based on the progress to date and currently planned products, what suggestion(s) or recommendation(s) does the Subcommittee offer on HERA's research to advance methods for systematic review? [Research Area 3, Output 3.4]

Charge Question 3:

Dose-response modeling is a critical step in human health assessment. Existing methods have improved upon older methodologies; however, unresolved issues, uncertainties, and complications remain that require targeted research. HERA has planned research products that will result in dose-response methods that are more precise, robust, and meet varied needs. Noting the examples provided, please comment on the extent to which

these planned products address important issues in dose-response modeling for application to risk assessment, and ways this research might be augmented? What suggestion(s) or recommendation(s) does the Subcommittee offer to continue to advance methods in dose-response modeling with an application to risk assessment? [Research Area 3, Output 3.5 and Research Area 4, Output 4.1]

CSS STAR Extramural Research Program

The Science to Achieve Results (STAR) Program is EPA's primary competitive, peer-reviewed, extramural research program. It funds nationally relevant research, leverages a wide variety of scientific and engineering resources, and provides collaborative access to innovative academics. Requests for Application (RFAs) originate in the EPA Office of Research and Development in cooperation with other Agency offices.

The **Safer Chemicals Research** grants align with the core mission of EPA's Chemical Safety for Sustainability (CSS) National Research Program to make informed and timely decisions concerning potential impacts of environmental chemicals on human health and the environment. A selection of recent Safer Chemicals Research RFAs is included below.

Assessment Tools for Biotechnology Products (FY2020 RFA)

Awards forthcoming

Advancing Toxicokinetics for Efficient and Robust Chemical Evaluations (FY2019 RFA)

Integrated blood brain barrier-computational model development to predict doses of concern for compound linked neurotoxicity

Purdue University 2020-2023

Measuring Toxicokinetics for Organ-on-Chip Devices Vanderbilt University

2020-2023

Integrating tissue chips, rapid untargeted analytical methods and molecular modeling for toxicokinetic screening of chemicals, their metabolites and mixtures

Texas A&M University

2020-2023

Toxicokinetic screening of zebrafish cytochrome P450 enzymes for in vitro-in vivo extrapolation Woods Hole Oceanographic Institution 2020-2023

An in vitro-in silico hybrid approach for high-throughput estimation of trans-barrier permeability for chemical pollutants

University of Nevada – Reno 2020-2023

Advancing Actionable Alternatives to Vertebrate Animal Testing for Chemical Safety Assessment (FY2018 RFA) (Focus on New Approach Methodologies (NAMs))

Skeletal Teratogenicity of Industrial and Environmental Chemicals Predicted with Human Pluripotent Stem Cells in Vitro

University of California – Riverside 2019-2022

A Neurovascular Unit on Chip for Reducing Animals in Organophosphate Neurotoxicology Vanderbilt University 2019-2022

Instrumenting phenotypic immunological responses to toxicants that threaten human reproduction Vanderbilt University Medical Center 2019-2022

Multiplexed human BrainSphere Developmental Neurotoxicity Test for Six Key Events of Neural Development

The Johns Hopkins University

2019-2022

Reducing the reliance on early-life stage testing with relevance to euryhaline fishes: Development and implementation of in-vitro assays predictive of early life stage toxicity and population-level effects in *Menidia beryllina*

Louisiana State University, Oregon State University

2019-2022

Systems-Based Research for Evaluating Ecological Impacts of Manufactured Chemicals (FY2014 RFA)

Integrated Modeling Approaches to Support Systems-Based Ecological Risk Assessment
Harvard University, President and Fellow of Harvard Collee, Washington State University 2015-2018

System Toxicological Approaches to Define Flame Retardant Adverse Outcome Pathways
Oregon State University 2015-2019

A Bioenergetics-Based Approach to Understanding and Predicting Individual- to Community-Level Ecological Effects of Manufactured Chemicals

Towson University

2015-2020

Development of a larval fish neurobehavior adverse outcome pathway to predict effects of contaminants at the ecosystem level and across multiple ecologically relevant taxa

Michigan State University

2015-2021

Linking Biological Scales Across Generations: An Estuarine and Marine Model for Measuring the Ecological Impact of Endocrine Disrupting Compounds
Oregon State University 2015-2020

Dynamical Systems Models Based on Energy Budgets for Ecotoxicological Impact Assessment
University of California – Santa Barbara 2015-2019

Organotypic Culture Models for Predictive Toxicology Center (FY2013 RFA) (Focus on Organs on a Chip)
Human Models for Analysis of Pathways (H MAPs) Center
University of Wisconsin Madison
2014-2019

Cardiotoxicity Adverse Outcome Pathway: Organotypic Culture Model and in vitro- to in-vivo Extrapolation for High-throughput Hazard, Dose-response and Variability Assessments

Texas A&M University

2015-2021

Predictive Toxicology Center for Organotypic Cultures and Assessment of AOPs for Engineered
Nanomaterials
University of Washington
2014-2020

Vanderbilt-Pittsburgh Resource for Organotypic Models for Predictive Toxicology
University of Pittsburgh, Vanderbilt University 2014-2019

Full listing of Safer Chemicals Research grants

CSS Highlights and Notable Accomplishments

2019 - Present

Top 14 Most Published in Journals

	Journal Impact	# of CSS
Title	Factor	Publications
1. Toxicological Sciences	3.703	32
2. Environmental Toxicology and Chemistry	3.152	25
3. Environmental Science & Technology	7.864	18
4. Science of the Total Environment	6.551	12
5. Computational Toxicology	2.11	11
6. Toxicology in Vitro	2.959	9
7. Environmental Health Perspectives	8.341	8
8. Regulatory Toxicology and Pharmacology	2.652	8
9. Environmental Science: Nano	7.683	7
10. Aquatic Toxicology	4.346	6
11. Analytical and Bioanalytical Chemistry	3.637	6
12. Journal of Exposure Science & Environmental Epidemio	logy 3.531	6
13. Chemosphere	5.778	6
14. PLoS ONE	2.74	6

Total Number of Publications

2019	2020	2021 (as of 1/14/2021)
153	133	13

CSS Publications Receiving External Recognition

Society of Toxicology's Best Postdoctoral Publication Award, 2021

Nyffeler J, Willis C, Lougee R, et al. (2020). <u>Bioactivity screening of environmental chemicals using imaging-based high-throughput phenotypic profiling</u>. *Toxicol Appl Pharmacol*, 389, 114876.

American Chemical Society Editor's Choice Award, November 2020

Richard AM, Huang R, Waidyanatha S, et al. (2020). The Tox21 10K Compound Library: Collaborative Chemistry Advancing Toxicology. Chem Res Toxicol.

The Society of Environmental Toxicology and Chemistry Exceptional Paper Award, June 2020

Villeneuve DL, Coady K, Escher BI, et al. (2019). <u>High-throughput screening and environmental risk assessment: State of the science and emerging applications</u>. *Environ Toxicol Chem*, 38(1), 12-26.

Computational Toxicology Specialty Section of the Society of Toxicology, Paper of the Year, 2019 Toxicological Sciences Paper of the Year: Honorable Mention, 2019

Wambaugh JF, Hughes MF, Ring CL, et al. (2018). Evaluating In Vitro-In Vivo Extrapolation of Toxicokinetics. Toxicol Sci, 163(1), 152-169.

Best Paper Advancing the Science of Risk Assessment, from the Risk Assessment Specialty Section of the Society of Toxicology, 2018

Phillips KA, Wambaugh JF, Grulke CM, et al. (2017). <u>High-throughput screening of chemicals as functional substitutes using structure-based classification models</u>. *Green Chemistry*, 19(4), 1063-1074.

International Society of Exposure Science Award for Best Journal of Exposure Science and Environmental Epidemiology Paper. 2018

Morgan MK, MacMillan DK, Zehr D, Sobus JR (2018). <u>Pyrethroid insecticides and their environmental degradates in repeated</u> duplicate-diet solid food samples of adults. *J Expo Sci Environ Epidemiol, 28, 40-45*.

Included in the Best of the Journal of Exposure Science and Environmental Epidemiology 2018-2019 Special Collection Sobus JR, Wambaugh JF, Isaacs KK, et al. (2018). <u>integrating tools for non-targeted analysis research and chemical safety evaluations at the US EPA. J Expo Sci Environ Epidemiol, 28, 411-426.</u>

CSS Investigators Receiving External Recognition

The Society of Toxicology's Enhancement of Animal Welfare Award, 2021

In recognition of contributions made to the advancement of toxicological science through the development and application of methods that replace, refine, or reduce the need for experimental animals.

Dr. Barbara Wetmore Center for Computational Toxicology and Exposure

LUSH Prize for Young Investigators, 2020

Supporting initiatives to end or replace animal testing.

Project: High-throughput phenotypic profiling of human neural progenitor cells to identify putative modes-of-action of developmental neurotoxicants

Dr. Johanna Nyffeler Center for Computational Toxicology and Exposure

Presidential Early Career Award for Scientists and Engineers (PECASE) Award, 2019

The highest honor bestowed by the U.S. government on outstanding scientists and engineers beginning their independent careers.

Dr. Carlie LaLone Center for Computational Toxicology and Exposure
Dr. Jon Sobus Center for Computational Toxicology and Exposure

SETAC Presidential Citation for Exemplary Service, 2018

For planning and chairing the SETAC North America Focused Topic Meeting "High Throughput-Screening and Environmental Risk Assessment"

Dan Villeneuve Center for Public Health and Environmental Assessment